Remarks/Arguments

Claims 16, 20 – 24, and 27 – 28 remain in this application. Claims 17 – 19, 25 – 26, and 29 – 30 have been canceled.

Claim 16, as amended, discloses a method for the administration of therapeutic amount of a growth factor protein formulation in the treatment of a patient displaying the symptoms of acute coronary artery disease comprising the steps of: (a) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof by inhalation therapy; (b) monitoring one or more clinical indicators of acute coronary artery disease; (c) determining, based on monitoring the one or more clinical indicators of acute coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary; (d) depending on the results of step c), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF1, FGF-2, VEGF, and mixtures thereof; and (e) repeating steps b) through d) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Claim 24, as amended, recites substantially the same limitations as present claim 16, except that present claim 24 discloses a method for use in the treatment of chronic coronary artery disease, as opposed to acute coronary artery disease.

Claims 16, 20-24, and 27-28 were rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 11-15 and 20 of U.S. Patent No. 6,759,386 (July 2004) Franco. The Examiner has indicated that the instant rejection is a statutory type double patenting rejection.

Applicant respectfully traverses this rejection. MPEP 804(II)(A) states that a reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Applicant submits that independent claim 16 of the present application does not require the method step of "selecting a patient displaying symptoms of acute coronary artery disease". Similarly, independent claim 24 of the present application does not require the method step of "selecting a patient displaying symptoms of chronic coronary artery disease". Therefore, independent claims 16 and 24, respectively, could be literally infringed without literally infringing a corresponding claim in the '386 patent, that is by not having the additional step of "selecting a patient displaying symptoms of (acute or coronary) artery disease."

For example, consider the following two different scenarios: (1) a patient feels chest pain and loss of breath and sees a physician; and (2) a patient is admitted into the hospital after test results confirm coronary artery disease.

In the first scenario, the physician must first evaluate the patient to determine the exact cause of the symptoms, i.e. the physician may not find that the symptoms

are caused by coronary artery disease. If, however, the physician determines that the patient is suffering from coronary artery disease, then at that point the physician can first select that patient for treatment, and then proceed with the treatment of that patient according to the method claims in the '386 patent.

In the second scenario, the physician need not perform the method step of selecting a patient with coronary artery disease, since it has already been established that the subject patient is suffering from said disease. In this situation, the physician could practice the method of independent claims 16 and 24, without literally infringing the claims of the '386 patent.

Therefore, it is submitted that (1) practicing a method for the treatment of coronary artery disease having the step of "selecting a patient displaying symptoms of coronary artery disease" is a different embodiment than (2) practicing such a method without being required to perform the step of "selecting a patient displaying symptoms of coronary artery disease". Because the present claims represent a separate embodiment when compared with the claims in the '386 patent, it is submitted that a statutory double patenting rejection is not appropriate. Further, it is submitted that the step of "selecting a patient displaying symptoms of coronary artery disease" is essential to the '386 patent, *see* MPEP 806.03, and important when a physician sees a patient who is exhibiting certain symptoms, yet at that moment the physician is uncertain whether those symptoms are being caused by coronary artery disease and whether or not treatment under the method claims of the '386 patent

would be appropriate. In other situations, however, the physician already knows that the patient is suffering from coronary artery disease (such as a diagnosis by an earlier physician), in which case the embodiment defined by present claims 16, 20 – 24, and 27 – 28 would be the appropriate method of treatment.

Simply put, present claims 16, 20 – 24, and 27 – 28 do not represent the "same invention" as the claims in the '386 patent, since they do not include identical subject matter. *See* MPEP 804(II)(A). Applicant submits that at most there exists a nonstatutory obviousness-type double patenting situation between present claims 16, 20 – 24, and 27 – 28 and the '386 patent. Applicant is willing to submit a Terminal Disclaimer, if the Examiner finds that such submission would be appropriate.

Accordingly, reconsideration of the rejection of present claims 16, 20 – 24, and 27 – 28 under 35 U.S.C. 101, as claiming the same invention as that of claims 1, 11-15 and 20 of U.S. Patent No. 6,759,386 (July 2004) Franco is respectfully requested.

Conclusion

In view of the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the rejection and allowance of present claims 16, 20 – 24, and 27 – 28 are earnestly solicited.

Respectfully submitted,
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